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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,024	07/22/2003	Tomio Kimura	03350CIP/HG	9538
1933	7590	01/21/2005	EXAMINER	
FRISHAUF, HOLTZ, GOODMAN & CHICK, PC 767 THIRD AVENUE 25TH FLOOR NEW YORK, NY 10017-2023			HUANG, EVELYN MEI	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,024

Applicant(s)

KIMURA ET AL.

Examiner

Evelyn Huang

Art Unit

1625

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
4a) Of the above claim(s) 50-69 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-49 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-69 are pending.

Election/Restrictions

2. In response to the restriction requirement mailed on 10-19-2004, Applicant has elected with traverse the invention of Group I, claims 24, 36-46, and claims 1-23, 25-35, 47-49 in part. The species elected is the compound of claim 41.

Applicants maintain that Groups I-IV, V-VI and IX-X should be examined together. Since Groups I-IV are all classified in class 548, Groups V-VI are all classified in Group 549, and Group IX-X are all classified in class 544.

On the contrary, the compounds of Groups I-X are structurally, chemically and patentably distinct. Although Groups I-IV are all in class 548, Group V-VI are all in class 549, and Group IX-X are all in class 544, they are different compounds belonging to different subclasses. Indeed there are 969 subclasses in class 548, 563 subclasses in class 549 and 410 subclasses in class 544. A reference anticipating a pyrazole compound of Group I would not render obvious the imidazole of Group II, the isoxazole of Group III, the isothiazole of Group IV, the furan of Group V, the thiophene of Group VI, the pyridazine of Group IX or the pyrimidine of Group X. The search is not co-extensive and is therefore burdensome. Since the search required for one group is not required for the other groups of inventions, restriction for examination purposes as indicated is proper.

The election of species is for examination purposes. The procedure set forth in MPEP 806.04(d) would be followed.

Priority

3. Applicants' claim for foreign priority under 35 USC 119 is acknowledged. Receipt of the certified copies of the priority documents filed on July 22, 2003 is also acknowledged.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-49, the 'ester and other derivative' is open-ended and is therefore indefinite. Its deletion is recommended.

b. Claim 1, definition of R2, 'a heteroaryl group which has at least one ring nitrogen atom' is repeated twice. Furthermore, 'at least one' is open-ended when the size and the specific heteroatoms in the heteroaryl are not recited in the claim.

The rejection is applicable to claims dependent on the above claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30, 32-36, 48, 49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds of claims 31, 37-47, does not reasonably provide enablement for making all the compounds encompassed by claims 1-30, 32-36, 48, 49. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

a. *Nature of the invention.*

The instant invention is drawn to a pyrazolyl compound for inhibiting the production of chemokine.

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b. *Predictability/unpredictability of the art.*

Unlike the mechanical art, The high degree of unpredictability is well recognized in the chemical art and the pharmaceutical art. A small change in the structure would drastically affect its biological activity.

d. *Amount of guidance/working examples.*

The preparation of examples is limited to compounds wherein R1 is optionally substituted phenyl, R2 is optionally substituted pyridinyl or pyrimidinyl and Ring B of R3 is a 5-7-membered saturated or partially saturated ring containing 1 nitrogen, optionally further fused with a phenyl or cyclohexyl.

Starting materials and the processes of making the instantly claimed compounds other than the example compounds, especially those wherein ring B of R3 has additional heteroatom(s) and further fused with a heteroaryl are not seen but required. Sources are particularly pertinent especially when the structures of these compounds are not fully described. Absent sources, the public is offered mere language, rather than enablement. Ex parte Moersch 104 USPQ 122. In re Howarthe 210 USPQ 689.

e. *The breadth of the claims.*

The claims embraces compounds wherein the substituents are any aryl or heteroaryl further substituted with multiple substituents, which may in turn further substituted with one or more substituents, and are structurally removed from the example compounds. The scope of the claims does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability in the chemical synthetic art and the limited working examples (paragraphs b, c, d above).

f. *Quantitation of undue experimentation.*

Since insufficient teaching and guidance have been provided in the disclosure, one of ordinary skill in the art, even with high degree of skill, would not be able to make all the compounds as claimed without undue experimentation.

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Claim Objections

6. Claims 1-23, 25-35, 47-49 are objected to because they contain non-elected subject matter.

Allowable Subject Matter

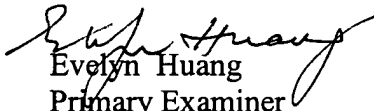
7. The compound of claims 31, 37-46, 47, and the composition thereof, are allowable subject matter.

Anantanarayan (WO 00/31063, PTO-1449) discloses a p38 kinase inhibiting pyrazolyl compound. The closest prior art compounds (pages 390-391, Example A-388, 389; page 1157) has a monocyclic nitrogen containing moiety instead of the instant bi- or tricyclic nitrogen containing moiety of formula IIa, IIb or IIc as R3. Absent is the motivation to modify the prior art compound to arrive at the instant invention.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
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